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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX-DGC **ORDER AND SUGGESTION OF REMAND**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases brought against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard manufactures and markets medical devices, including inferior vena cava ("IVC") filters. The MDL Plaintiffs have received implants of Bard IVC filters and claim that they are defective and have caused Plaintiffs to suffer serious injury or death.

The MDL was transferred to this Court in August 2015 when 22 cases had been filed. Doc. 1. To date, more than 4,000 cases have been filed. The Court has concluded that 10 mature cases listed on Schedule A should be remanded to the transferor courts. Doc. 11659 at 5. The Court therefore provides this Suggestion of Remand to the United States Judicial Panel for Multidistrict Litigation (the "Panel").

To assist the transferor courts on remand, if ordered by the Panel, this order describes events that have taken place in the mature cases and the MDL as a whole. A copy of this order, along with the case files and materials, will be available to the transferor courts after remand.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. An IVC filter is a small device implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves multiple versions of Bard IVC filters – the Recovery, G2, G2X, Eclipse, Meridian, and Denali. These are umbrella-shaped devices that have multiple limbs fanning out from a cone-shaped head. The limbs consist of legs with hooks that attach to the IVC wall and curved arms to catch or break up blood clots. Each of these filters is a variation of its predecessor.[1]

The MDL Plaintiffs allege that Bard filters are more dangerous than other IVC filters because they have higher risks of tilting, perforating the IVC, or fracturing and migrating to vital organs. Plaintiffs further allege that Bard failed to warn patients and physicians about these higher risks. Defendants dispute these allegations, contending that Bard filters are safe and effective, that their complication rates are low and comparable to those of other IVC filters, and that the medical community is aware of the risks associated with IVC filters.

As noted, more than 4,000 cases have been filed in this MDL since its inception in 2015. By late 2017, the parties completed all common discovery and filed dispositive and *Daubert* motions. The Court has ruled on Defendants' motion for summary judgment on preemption grounds, decided more than a dozen *Daubert* motions, and resolved summary judgment motions in four bellwether cases. Two bellwether cases were tried earlier this year. One other bellwether case is set for trial this month, and two more in 2019. No cases have settled.

II. Suggestion of Remand.

A. Remand Standard.

The power to remand MDL cases rests solely with the Panel. 28 U.S.C. § 1407(a);

[1] For further discussion of IVC filters and their uses, see the Court's order addressing Defendants' summary judgment motion on preemption. Doc. 8872 at 1-2.

see Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach, 523 U.S. 26, 28 (1998). The Panel typically relies on the transferee court to suggest when it should order remand. J.P.M.L. Rule 10.1(b)(i); *see In re Motor Fuel Temperature Sales Practices Litig.*, No. 07-MD-1840-KHV, 2012 WL 1963350, at *1 (D. Kan. May 30, 2012). Indeed, the Panel "is reluctant to order a remand absent the suggestion of the transferee judge[.]" J.P.M.L. Rule 10.3(a); *see In re Regions Morgan Keegan Sec., Derivative & ERISA Litig.*, No. 2:09-md-2009-SHM, 2013 WL 5614285, at *2 (W.D. Tenn. Feb. 28, 2013). The transferee court may suggest to the Panel that cases be remanded where they are "ready for trial, or . . . would no longer benefit from inclusion in the coordinated or consolidated pretrial proceedings." *In re Multi-Piece Rim Prods. Liab. Litig.*, 464 F. Supp. 969, 975 (J.P.M.L. 1979); *see In re TMJ Implants Prods. Liab. Litig.*, 872 F. Supp. 1019, 1038 (D. Minn. 1995).

B. Ten Mature Cases Should Be Remanded.

In October 2015, the parties identified 13 cases that were sufficiently advanced to be considered for remand. Doc. 174 at 7-9; *see* Doc. 363 at 2-3. These cases were designated as "mature cases" in the Court's initial orders. Docs. 519 at 3, 914 at 2. Although the mature cases were more advanced than other cases in the MDL, the parties agreed that they should not be remanded immediately, but instead should remain part of the MDL as possible bellwether cases. Doc. 249 at 6.

In February 2016, the Court directed the parties to confer and identify the specific discovery, motion practice, and other litigation steps needed for the mature cases. Doc. 519 at 3. The purpose was to remand these cases as soon as reasonably possible, rather than postponing their disposition until the end of the MDL proceeding. *Id.*

In April 2016, the parties agreed that 3 of the 13 cases should no longer be deemed mature and instead should be treated like all other cases in this MDL. Doc. 1319 at 2. The remaining 10 cases, listed below, continue to be designated as mature cases:

- *Tillman v. C. R. Bard, Inc.*, No. 3:13-cv-0222 (M.D. Florida)
- *Ocasio v. C. R. Bard, Inc.*, No. 8:13-cv-01962 (M.D. Florida)

- *Cason v. C. R. Bard, Inc.*, No. 1:12-cv-01288 (N.D. Georgia)
- *Coker v. C. R. Bard, Inc.*, No. 1:13-cv-00515 (N.D. Georgia)
- *Rivera (McClarty) v. C. R. Bard, Inc.*, No. 4:14-cv-13627 (E.D. Michigan)
- *Ebert v. C. R. Bard, Inc.*, No. 5:12-cv-01253 (E.D. Pennsylvania)
- *Keen v. C. R. Bard, Inc.*, No. 5:13-cv-05361 (E.D. Pennsylvania)
- *Smith v. C. R. Bard, Inc.*, No. 1:13-cv-00633 (E.D. Texas)
- *Fox v. C. R. Bard, Inc.*, No. 3:14-cv-00133 (N.D. Texas)
- *Henley v. C. R. Bard, Inc.*, No. 2:14-cv-00059 (E.D. Wisconsin)

Id.[2]

In August 2016, the parties stipulated that remand of the mature cases should await completion of expert discovery because such discovery may be relevant in trials of the mature cases. Doc. 3214 at 3. The Court agreed, concluding that general expert disclosure and discovery, and any related *Daubert* motions, should be handled in this MDL. Doc. 4311 at 2. The Court further concluded that case-specific discovery in the mature cases should await their remand. *Id.*; *see* Doc. 8871 at 5.

Following the second bellwether trial earlier this year, the Court directed the parties to file memoranda addressing the appropriate time for remand of the mature cases. Doc. 11320 at 3. Defendants argued that the cases should be remanded in 2019 after completion of the remaining bellwether trials. Doc. 11550 at 5-6. Plaintiffs argued that the cases should be remanded now because retaining the cases in the MDL will provide no additional benefits and there is no reason to delay. Doc. 11553 at 7.

The Court agrees with Plaintiffs. All common fact and expert discovery in this MDL have been completed, and the Court has ruled on *Daubert* motions and Defendants' summary judgment motion on preemption. The mature cases are nearly ready for trial and would no longer benefit from inclusion in this MDL. The remaining case-specific

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[2] The cases no longer designated as mature are *Conn v. C. R. Bard, Inc.*, No. 1:13-cv-00515 (N.D. Ga.), *Milton v. C. R. Bard, Inc.*, No. 5:14-cv-00351 (N.D. Ga.), and *Mintz v. C. R. Bard, Inc.*, No. 2:14-cv-04942 (E.D.N.Y). *Id.*

issues in the mature cases are best left to the transferor courts to resolve. The Court therefore suggests that the Panel remand the 10 mature cases listed on Schedule A to the transferor courts for further proceedings. *See In re TMJ Implants*, 872 F. Supp. at 1038 (suggesting remand of cases that no longer benefited from inclusion in consolidated pretrial proceedings).

III. The MDL Proceedings.

A summary of the MDL proceedings to date is provided below to assist the transferor courts on remand, if ordered by the Panel. Case management orders, discovery orders, and other significant rulings are listed in Exhibit 1. The status of the remaining case-specific discovery and other pretrial issues for the mature cases, and the estimated time needed to resolve such issues and make the cases ready for trial, as proposed by the parties, are listed in Exhibit 2.

A. Case Management Orders.

The primary orders governing pretrial management of this MDL are a series of case management orders ("CMOs"), along with certain amendments. To date, the Court has issued 36 CMOs. These orders are discussed below and can be found on the Court's website at http://www.azd.uscourts.gov/case-info/bard.

B. Lead and Liaison Counsel.

CMO No. 1, entered October 30, 2015, appointed Co-Lead/Liaison Counsel for Plaintiffs ("Lead Counsel") to manage the litigation on behalf of Plaintiffs, and set out the responsibilities of Lead Counsel. Doc. 248. Plaintiffs' Lead Counsel has changed since the inception of the MDL. Mr. Ramon Lopez, of Lopez McHugh, LLP, in Newport Beach, California, and Mr. Mark O'Connor, of Gallagher & Kennedy, P.A., in Phoenix, Arizona, are now Lead Counsel for Plaintiffs. Doc. 5285. Mr. Richard North of Nelson Mullins Riley & Scarborough, LLP, in Atlanta, Georgia, is Defendants' Lead Counsel.

C. Plaintiffs' Steering Committee and Common Benefits Fund.

CMO No. 1 directed the selection and appointment of a Plaintiffs' Steering Committee ("PSC") to assist in the coordination of pretrial activities and trial planning.

Plaintiffs' Lead Counsel and the PSC together form the Plaintiffs' Leadership Counsel ("PLC"). The PSC acts on behalf of, and in consultation with, Plaintiffs' Lead Counsel in the management of the litigation. The PLC assists all Plaintiffs in the MDL by overseeing discovery, appearing in court, attending status conferences, and preparing motions and responses regarding case-wide discovery matters. CMO No. 1 has been amended to select and appoint a Plaintiffs' Executive Committee ("PEC") to assist Lead Counsel in the administration, organization, and strategic decisions of the PLC. Doc. 4016. The configuration of the PSC has changed during the course of the litigation. *See* Docs. 248, 4016, 5285.

CMO No. 6, entered December 18, 2015, set forth rules, policies, procedures, and guidelines for fees and expenses incurred by attorneys acting for the common benefit of all MDL Plaintiffs. Doc. 372.

D. Master and Short-Form Pleadings.

CMO No. 2, entered October 30, 2015, required the creation of a master complaint, a master answer, and templates of short-form complaints and answers. Doc. 249 at 6. The master complaint and answer were filed December 12, 2015. Docs. 364, 366. They are the operative pleadings for most of the cases in this MDL. The master complaint serves as a long-form complaint giving notice, pursuant to Rule 8, of the allegations that the MDL Plaintiffs assert generally. Doc. 364. The master complaint asserts 17 claims and seeks both compensatory and punitive damages. *Id.* ¶¶ 166-349.

Plaintiff-specific allegations are contained in individual short-form complaints (Doc. 303-2) or certain complaints served on Defendants before the filing of the master complaint. Plaintiffs also provide Defendants with profile forms and fact sheets that describe their individual conditions and claims. Doc. 365 (CMO No. 5, as amended by Doc. 927).

The 10 mature cases listed on Schedule A are not governed by the master complaint, but continue to be governed by the complaints and answers (including any amended pleadings) filed in the various transferor courts before the cases were

transferred to this MDL. Doc. 363 (CMO No. 4, as amended by Doc. 1485). The parties were not required to exchange profile forms in the mature cases. Doc. 365.

E. Status Conferences.

Since the inception of the MDL, the Court has held regular status conferences with Lead Counsel for the parties to discuss issues related to the litigation. The initial case management conference was held in October 2015. Doc. 246. Deadlines were set for, among other things, the filing of master and short-form pleadings, profile forms, a proposed protective order (including Rule 502 provisions), a proposed protocol governing the production of electronically stored information ("ESI"), as well as deadlines to complete first-phase MDL discovery and address privilege log issues. Doc. 249 (CMO No. 2). Thereafter, the Court held periodic status conferences to ensure that the parties were on task and to address routine discovery issues and disputes. In addition to the status conferences, the Court conducted telephonic hearings to address time-sensitive issues, as well as numerous additional conferences to consider various matters such as hearings on dispositive motions and general case management issues.

F. Discovery.

1. General Fact Discovery.

Prior to the establishment of this MDL, Plaintiffs had conducted substantial common discovery against Bard (including in the mature cases) concerning all aspects of Bard IVC filters, including the design, testing, manufacturing, marketing, labeling, and post-market surveillance of these devices. Bard produced numerous documents and ESI, responded to thousands of written discovery requests, and more than 80 corporate witness depositions were taken. The pre-MDL general fact discovery was made available by Bard to all Plaintiffs in the MDL.

This MDL was formed to centralize pretrial proceedings and complete all common fact and expert discovery concerning Bard IVC filters. Doc. 1. CMO No. 8 established a procedure concerning re-deposing witnesses in the MDL. Doc. 519. CMO No. 14 established deposition protocols generally. Doc. 2239. The Court allowed additional

depositions of a handful of corporate witnesses that had been previously deposed, as well as numerous depositions of other Bard corporate witnesses, including several Rule 30(b)(6) depositions. Docs. 3685, 4311. CMO No. 9 governed the production of ESI and hard-copy documents. Doc. 1259.

Discovery in the MDL was separated into multiple phases. The parties completed the first phase of MDL discovery in early 2016. Doc. 519. First-phase MDL discovery included production of documents related to an FDA inspection and warning letter to Bard, an updated production of complaint and adverse event files, and an updated version of Bard's complaint database relating to IVC filters. Doc. 249. Plaintiffs also conducted a Rule 30(b)(6) deposition concerning the FDA inspection and warning letter, and a deposition of corporate witness Kay Fuller.

The parties completed the second phase of MDL fact discovery in February 2017. CMO No. 8 set deadlines for the second phase, which included all common fact and expert issues in the MDL, but not case-specific issues to be resolved after remand. Docs. 249, 519. Second-phase discovery included extensive additional discovery related to Bard's system architecture for ESI, Bard's ESI collection efforts, ESI relating to Bard's IVC filters, and Bard's national and regional sales and marketing practices. Plaintiffs also deposed two corporate witnesses in connection with Kay Fuller's allegations that a submission to the FDA regarding the Recovery filter did not bear her original signature. Doc. 1319 (CMO No. 10). Plaintiffs deposed additional corporate witnesses concerning the FDA inspection and warning letter. *Id.*

Bard also produced discovery regarding the sales and marketing materials related to the Simon Nitinol filter ("SNF"), documents comparing filter performance and failure rates to the SNF, and internal and regulatory communications relating to the SNF. Docs. 1319, 10489. The Court denied Plaintiffs' request to obtain ESI discovery from Bard's overseas operations. Doc. 3398. The Court denied Defendants' request to obtain discovery of communications between Plaintiffs' counsel and NBC related to NBC news stories about the products at issue in this litigation, and third-party financing that may be

in place with respect to Plaintiffs in this MDL. Docs. 3313, 3314. Plaintiffs were required to produce communications between Plaintiffs and the FDA related to the FDA warning letter, but the Court denied Defendants' request to depose Plaintiffs' counsel regarding these communications. Docs. 3312, 4339. Bard also produced punitive damages discovery, and Plaintiffs conducted a Rule 30(b)(6) deposition related to Bard's net worth.

All common fact discovery in these cases has now been completed. Thus, transferor courts need not be concerned with facilitating general fact discovery on remand.

2. Case-Specific Discovery.

The parties did not conduct case-specific fact discovery for the 10 mature cases during the MDL proceedings, but instead conducted such discovery in these cases prior to their transfer to the MDL. The Court has concluded that any additional case-specific discovery in the mature cases should await their remand. Docs. 3214 at 3, 8871 at 5. The status of the remaining case-specific discovery for the mature cases is listed in Exhibit 2.

3. Expert Discovery.

CMO No. 8 governed expert disclosures and discovery. Doc. 519. The parties designated general experts in all MDL cases, and case-specific experts in individual bellwether cases. General expert discovery closed on July 14, 2017. Doc. 3685. The parties conducted expert discovery in some of the mature cases prior to their transfer to the MDL. The status of the remaining case-specific expert discovery for the mature cases is listed in Exhibit 2.

4. Privileged Materials.

CMO No. 2 required Defendants to provide to Plaintiffs all privilege logs in compliance with the Federal Rules of Civil Procedure. Doc. 249. The parties were then required to engage in an informal privilege log meet and confer process to resolve any privilege disputes. Defendants produced several privilege logs identifying documents withheld pursuant to the attorney-client privilege, the work-product doctrine, and other

privileges. The parties regularly met and conferred regarding the privilege logs and engaged in negotiations regarding certain entries identified by Plaintiffs. As part of that meet and confer process, Defendants provided Plaintiffs with a small number of these identified items for inspection and, in some cases, withdrew certain claims of attorney-client privilege and produced the previously withheld items.

CMO No. 3 governed the non-waiver of any privilege or work-product protection in this MDL, pursuant to Federal Rule of Evidence 502(d), from Defendants' disclosure or production of documents on its privilege logs as part of the meet and confer process. Doc. 314.

In late 2015, Plaintiffs challenged a substantial number of documents on Defendants' privilege logs. The parties engaged in an extensive meet and confer process, and Defendants produced certain documents pursuant to the Rule 502(d) order. Doc. 314. Plaintiffs moved to compel production of 133 disputed documents. The Court granted the motion in part. Doc. 2813. The parties identified several categories of disputed documents and provided sample documents to the Court for *in camera* review. The Court denied Plaintiffs' motion with respect to seven out of the eight categories of documents and found only one of the sample documents in one of the categories to contain unprivileged portions that should be produced. The Court found all other documents protected by the attorney-client privilege or work product doctrine. The Court directed the parties to use this ruling as a guide to resolve the remaining privilege disputes.

Since this ruling, there have been no further challenges to Defendants' privilege logs. Defendants continued to provide updated privilege logs throughout the discovery process, and the parties met and conferred to resolve privilege disputes. Privilege issues should not be a concern for any transferor court on remand.

5. Protective Order and Confidentiality.

A stipulated protective order governing the designation, handling, use, and disclosure of confidential discovery materials was entered in November 2015. Doc. 269.

CMO No. 7, entered January 5, 2016, governed redactions of material from additional adverse event reports, complaint files, and related documents in accordance with the Health Insurance Portability Act of 1996 ("HIPAA") and under 21 C.F.R. § 20.63(f). Doc. 401.

In September 2016, to expedite production of ESI, the parties agreed to a primarily "no-eyes-on" document production as to relevancy while still performing a privilege review for this expedited ESI document production. CMO No. 17 (Doc. 3372) modified the protections and requirements in the stipulated protective order (Doc. 269) and CMO No. 7 (Doc. 401) for ESI produced pursuant to this process. CMO No. 17 was amended in November 2016. Doc. 4015.

G. Bellwether Cases and Trials.

CMO No. 11, entered May 5, 2016, provided for the selection of individual Plaintiffs who would be subject to case-specific discovery and eligible to be part of the bellwether trial process. Doc. 1662. From that group, six cases were selected for bellwether trials. Docs. 5770 (CMO No. 23), 11659 (CMO No. 34). To date, the Court has presided over two bellwether trials: *Booker v. C. R. Bard, Inc.*, No. CV-16-00474, and *Jones v. C. R. Bard, Inc.*, No. CV-16-00782. The Court granted summary judgment in one of the bellwether cases (Doc. 12202), and three other bellwether trials will be held in September 2018 and February and May 2019 (Docs. 11871, 12061 (CMO Nos. 35, 36)).

1. *Booker v. C. R. Bard, Inc.*, No. CV-16-00474.

The first bellwether trial concerned Plaintiff Sherr-Una Booker and involved a Bard G2 filter. The filter had tilted, migrated, and fractured. Plaintiff required open heart surgery to remove the fractured limbs and repair heart damage caused by a percutaneous removal attempt. The Court granted in part Defendants' motion for summary judgment. Docs. 8873, 8874. The claims for failure to warn, design defect, and punitive damages were tried to a jury over a three-week period in March 2018.

The jury found for Plaintiff Booker on her negligent failure-to-warn claim, and in

favor of Defendants on the design defect and strict liability failure-to-warn claims. Doc. 10595. The jury returned a verdict of $2 million in compensatory damages (of which $1.6 million was attributed to Defendants) and $2 million in punitive damages. *Id.*; Doc. 10596. The Court denied Defendants' motion for judgment as a matter of law and motion for a new-trial. Docs. 10879, 11598. Defendants have appealed to the Ninth Circuit. Docs. 11934, 11953. Plaintiff has cross-appealed. Doc. 12070.

2. *Jones v. C. R. Bard, Inc.*, No. CV-16-00782.

The second bellwether trial concerned Plaintiff Doris Jones and involved a Bard Eclipse filter. The Court granted in part Defendants' summary judgment motion. Doc. 10404. The claims for failure to warn, design defect, and punitive damages were tried to a jury over a three-week period in May 2018. The jury returned a defense verdict. Doc. 11350. Plaintiff has appealed. Docs. 12057, 12071.

3. *Kruse v. C. R. Bard, Inc.*, Case No. CV-15-01634.

Plaintiff Carol Kruse's case was set for trial in September 2018. The Court granted Defendants' summary judgment motion on statute of limitations grounds. Doc. 12202.

4. Other Scheduled Bellwether Trials.

Plaintiff Lisa Hyde's case, *Hyde v. C. R. Bard, Inc.*, No. CV-16-00893, was moved to the September 2018 bellwether slot in lieu of Ms. Kruse's case. Doc. 11867. Two other bellwether cases are set for trial in February and May 2019. The Court plans to try *Tinlin v. C. R. Bard, Inc.*, No. CV-16-00263, and *Mulkey v. C. R. Bard, Inc.*, CV-16-00853. Doc. 12061. The Court has yet to determine the order of the trials.

H. Key Legal and Evidentiary Rulings.

The Court has made many significant rulings in this MDL, some of which affect the mature cases. The Court provides the following summary of key legal and evidentiary rulings to assist the transferor courts on remand.

1. Medical Monitoring Class Action Ruling.

In May 2016, Plaintiffs' counsel filed a medical monitoring class action that was

consolidated with the MDL. *See Barraza v. C. R. Bard, Inc.*, No. CV-16-01374. The *Barraza* Plaintiffs moved for class certification for medical monitoring relief on behalf of themselves and classes of individuals who have been implanted with a Bard IVC filter, have not had that filter removed, and have not filed a claim or lawsuit for personal injury related to the filter. *Id.*, Doc. 54. The Court denied the motion. *Id.*, Doc. 95.

The class certification motion recognized that only 16 states permit claims for medical monitoring. The Court concluded that the classes could not be certified under Federal Rule of Civil Procedure 23(b)(3) because individual issues would predominate. *Id.* at 20-21.[3] The Court further concluded that the class could not be certified under Rule 23(b)(2) because the medical monitoring relief primarily constituted monetary rather than injunctive relief, and the class claims were not sufficiently cohesive to permit binding class-wide relief. *Id.* at 21-32. Finally, the Court concluded that typicality under Rule 23(a)(3) had not been established. *Id.* at 32-34. The *Barraza* Plaintiffs ultimately dismissed their claims without prejudice. Docs. 106, 107. No appeal has been filed.

2. Federal Preemption Ruling.

Defendants moved for summary judgment on the grounds that Plaintiffs' state law claims are expressly preempted by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360 et seq., and impliedly preempted by the MDA under the Supreme Court's conflict preemption principles. Doc. 5396. The Court denied Defendants' motion. Doc. 8872. Defendants have appealed this ruling. Docs. 11934, 11953.

The MDA curtails state regulation of medical devices through a provision that preempts state requirements that differ from or add to federal requirements. 21 U.S.C.

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[3] These individual issues would arise from several key elements of the *Barraza* Plaintiffs' claims: (1) whether Bard was negligent in the design of various generations of filters; (2) whether Bard was negligent in failing to disclose risks for various kinds of filters at various points in time; (3) whether the learned intermediary defense applies; (4) whether assumption of risk or contributory or comparative negligence applies; (5) whether the proposed medical monitoring is necessary and distinct from the ordinary course of treatment the class member is receiving; and (6) what state law should apply to each class member's claim. *Id.*

§ 360k. The Bard IVC filters at issue in this litigation were cleared for market by the FDA through section "510k" review, which focuses primarily on equivalence rather than safety and effectiveness. *See* § 360c(f)(1)(A).

The Supreme Court in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), held that § 360k does not preempt state law claims directed at medical devices cleared through the 510(k) process because substantial equivalence review places no federal requirements on a device. *Id.* at 492-94. *Lohr* also noted that the "510(k) process is focused on *equivalence*, not safety." *Id.* at 493 (emphasis in original). Although the Safe Medical Devices Act of 1990 ("SMDA"), Pub. L. 101-629, introduced safety and effectiveness considerations into 510(k) review, it did so only comparatively. The Court found that *Lohr* remains good law, and that clearance of a product under 510(k) generally does not preempt state common law claims. Doc. 8872 at 12-14.

The Court found that Defendants failed to show that the 510(k) reviews for Bard IVC filters imposed device-specific requirements as needed for preemption under § 360k. *Id.* at 14-20. Even if device-specific federal requirements could be ascertained, Defendants made no showing that any particular state law claim is expressly preempted by federal requirements. *Id.* at 21-22.

The Court further found that Plaintiffs' state law claims are not impliedly preempted because Defendants failed to show that it is impossible to do under federal law what state laws require. *Id.* at 22-24.

3. The Lehman Report Privilege and Work Product Rulings.

The Court granted Defendants' motion for a protective order to prevent Plaintiffs from using the December 15, 2004 report of Dr. John Lemann. Doc. 699. Dr. Lehmann provided various consulting services to Bard at different times. Following Bard's receipt of potential product liability claims involving the Recovery filter, Bard's legal department retained Dr. Lehmann in November 2004 to provide an assessment of the risks associated with the Recovery filter and the extent of Bard's legal exposure. Dr. Lehmann prepared a written report of his findings at the request of the legal

department and in anticipation of litigation. The Court found the report to be protected from disclosure by the work product doctrine. *Id.* at 4-12. The Court further found that Plaintiffs had not shown a substantial need for the report or undue hardship if the report were not disclosed. *Id.* at 13-15. The Court agreed with the parties that this ruling does not alter any prior rulings by transferor judges in specific cases. *Id.* at 22.

4. *Daubert* Rulings.

The Court has ruled on the parties' *Daubert* motions and refers the transferor courts to the following orders:

***Daubert* Order**	**Doc. No(s).**
Order on Motion to Disqualify Plaintiffs' Expert Dr. Thomas Kinney	9428, 10323
Order on Motion to Disqualify Plaintiffs' Experts Drs. Scott Resnick, Robert Vogelzang, Kush Desai, and Robert Lewandowski	9432
Order on Motions to Exclude Opinions of Plaintiffs' Experts Drs. David Kessler and Suzanne Parisian	9433
Order on Motion to Exclude Opinions of Plaintiffs' Experts Drs. Thomas Kinney, Anne Christine Roberts, and Sanjeeva Kalva	9434
Order on Motion to Exclude Opinions of Plaintiffs' Expert Dr. Mark Eisenberg	9770
Order on Motion to Exclude Opinions of Plaintiffs' Expert Dr. Derek Muehrcke	9771
Order on Motion to Exclude Opinions of Plaintiffs' Expert Dr. Darren Hurst	9772
Order on Motion to Exclude Opinions of Plaintiffs' Expert Dr. Rebecca Betensky	9773

Order on Motion to Exclude Opinions of Defendants' Expert Dr. Clement Grassi	9991, 10230
Order on Motion to Exclude Opinions of Plaintiffs' Expert Dr. Robert McMeeking	10051
Order on Motion to Exclude Opinions of Plaintiffs' Expert Dr. Robert Ritchie	10052
Order on Motion to Exclude Opinions of Plaintiffs' Experts Drs. David Garcia and Michael Streiff	10072
Order on Motion to Exclude Opinions of Defendants' Expert Dr. Christopher Morris	10230, 10231

5. Motion in Limine Rulings.

a. FDA Evidence (*Cisson* Motion).

In the Booker bellwether trial, Plaintiffs sought to exclude, under Federal Rules of Evidence 402 and 403, evidence of FDA 510(k) clearance of Bard IVC filters and the lack of FDA enforcement action against Bard. Doc. 9529. The Court denied the motion. Docs. 9881, 10323.

The Court found that under Georgia Law, which applied in both the Booker and Jones bellwether cases, compliance with federal regulations may not render a manufacturer's design choice immune from liability, but evidence of Bard's compliance with the 510(k) process was nonetheless relevant to the design defect and punitive damages claims under Georgia law. Doc. 9881 at 3-4. The Court acknowledged concerns that FDA evidence might mislead the jury or result in a mini-trial. *Id.* at 5-6 (citing *In re C.R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig. (Cisson),* No. 2:10-CV-01224, 2013 WL 3282926, at *2 (S.D.W. Va. June 27, 2013)). But the Court concluded that such concerns could be adequately addressed by efficient management of the evidence and adherence to the Court's time limits for trial, and, if necessary, by a

limiting instruction regarding the nature of the 510(k) process. *Id.* at 6-7.[4]

The Court noted that the absence of any evidence regarding the 510(k) process would run the risk of confusing the jury, as many of the relevant events in this litigation occurred in the context of FDA 510(k) review and are best understood in that context. Doc. 9881 at 7. Nor was the Court convinced that all FDA-references could adequately be removed from the evidence. *Id.*

The Court further concluded that it would not exclude evidence and arguments by Defendants that the FDA took no enforcement action against Bard with respect to the G2 and Eclipse filters, or evidence regarding information Bard provided to the FDA in connection with the 510(k) process. Docs. 10323 at 2-3 (Booker), 11011 at 4-5 (Jones). The Court found that the evidence was relevant to the negligent design and punitive damages claims under Georgia law. *Id.* The Court determined at trial that it had no basis to conclude that the FDA's lack of enforcement was intended by the FDA as an assertion, and thus should not be barred as hearsay. *See* Trial Tr. Day 8, at 1681:1-6, *Booker v. C. R. Bard, Inc.* (D. Ariz. Mar. 26, 2018).

Finally, the Court held that Defendants would not be permitted to present evidence or argument that the FDA "approved" Bard filters for market, or that clearance of the devices under 510(k) review constitutes a finding by the FDA that the filters are "safe and effective." *Id.*; *see* 21 C.F.R. § 807.97.

b. FDA Warning Letter.

Defendants moved to exclude, under Federal Rules of Evidence 402 and 403, evidence of the July 13, 2015 FDA warning letter issued to Bard. Doc. 9864 at 2-3. The Court granted the motion in part, excluding as irrelevant topics 1, 2, 4(a), 4(b), 5, 6, 7, and 8 of the warning letter. Docs. 10258 at 6-8 (Booker), 10805 at 1 (Jones). Topics 1 and 2 concern the Recovery Cone retrieval system; Topic 4(a) concerns the filter cleaning

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[4] The Court did not find a limiting instruction necessary at the close of either the Booker or Jones bellwether trials. *See* Trial Tr. Day 11, at 2447:18-19, *Booker v. C. R. Bard, Inc.* (D. Ariz. Mar. 29, 2018).

process; and Topics 4(b), 5, 6, 7, and 8 concern the Denali Filter. The Court concluded that none of these topics was relevant to the issues in the first two bellwether cases involving a G2 filter (Booker) and an Eclipse filter (Jones). *Id.*

The Court found that topic 3, concerning Bard's complaint handling and reporting of adverse events with respect to the G2 and Eclipse filters, as well as the adequacy of Bard's evaluation for the root cause of the violations, was relevant to rebut the implication at trial that the FDA took no action with respect to Bard IVC filters. *See* Trial Tr. Day 9, at 1888:21 to 1892:25, *Booker v. C. R. Bard, Inc.* (D. Ariz. Mar. 27, 2018); Doc. 11256. The Court concluded that the warning letter was admissible under Federal Rule of Evidence 803(8), and thus should not be barred as hearsay. Doc. 10258 at 7. The Court further concluded that the probative value of topic 3 was not substantially outweighed by the danger of unfair prejudice to Bard under Rule 403. The Court admitted the warning letter in redacted form during the first two bellwether trials. *See* Docs. 10565, 11256.

c. Recovery Cephalad Migration Death Evidence.

Defendants moved to exclude, under Federal Rules of Evidence 402 and 403, evidence of cephalad migration (i.e., migration of the filter toward the patient's heart) by a Recovery filter resulting in patient death. The Court denied the motion for the Booker bellwether trial, which involved a G2 filter. Docs. 10258 at 4-5, 10323 at 4. Defendants have appealed this ruling. Docs. 11934, 11953.

The Court granted the motion for the Jones bellwether trial, which involved an Eclipse filter, and denied Plaintiff's requests for reconsideration of the ruling before and during trial. *See* Docs. 10819, 10920, 11041, 11113, 11256, 11302; *see also* Trial Tr. Day 10, at 2224:3 to 2226:24, *Jones v. C. R. Bard, Inc.* (D. Ariz. May 30, 2018). Plaintiff Jones has appealed those rulings. Docs. 12057, 12071.

The Court concluded for purposes of the Booker bellwether trial that evidence of cephalad migrations by the Recovery filter resulting in patient death was necessary for the jury to understand the issues that prompted the creation and design of the G2 filter,

and thus was relevant to Plaintiff's design defect claims. Doc. 10323 at 4. In addition, because the Recovery filter was the predicate device for the G2 filter in Defendants' 510(k) submission to the FDA, and Defendants asserted to the FDA that the G2 was as safe and effective as the Recovery, the Court concluded that the safety and effectiveness of the Recovery filter was at issue. *Id.* The Court was concerned, however, that too heavy an emphasis on deaths caused by cephalad migration of the Recovery filter – a kind of migration which did not occur in the G2 filter generally or the Booker case specifically – would result in unfair prejudice to Defendants that substantially outweighed the probative value of the evidence. *Id.* The Court monitored this issue during trial, but found that the death evidence was not over-emphasized by Plaintiffs.

The Court initially concluded for purposes of the Jones bellwether trial, which involved the Eclipse filter, that evidence of cephalad migration deaths by the Recovery filter was inadmissible because it was only marginally relevant to Plaintiff's claims. *See* Docs. 10819, 10920, 11041, 11113, 11256, 11302. This is because cephalad migration did not continue in any significant degree beyond the Recovery; cephalad migration deaths all occurred before the Recovery was taken off the market in late 2005; Ms. Jones did not receive her filter until 2010; the deaths said nothing about three of Ms. Jones' four claims (strict liability design defect and the failure to warn claims); and instances of cephalad migration deaths were not substantially similar to complications experienced by Ms. Jones and therefore did not meet the Georgia standard for evidence on punitive damages. Docs. 10819, 11041.

The Court also found that deaths caused by a non-predicate device (the Recovery was not the predicate device for the Eclipse in Defendants' 510(k) submission), and by a form of migration that was eliminated years earlier, were of sufficiently limited probative value that their relevancy was substantially outweighed by the danger of unfair prejudice because the death evidence may prompt a jury decision based on emotion. *Id.* The Court further concluded that Plaintiff Jones would not be seriously hampered in her ability to prove Recovery filter complications, testing, and design when references to cephalad

migration deaths are removed. Doc. 11041. As a result, the Court held that such references should be redacted from evidence to be presented during the Jones bellwether trial.

The Court made sure to balance this concern with the competing concern that it would be unfair for Defendants to present statistics about the Recovery filter and not allow Plaintiffs to present competing evidence that included Recovery deaths. *See, e.g.*, Trial Tr. Day 2, at 242:18 to 242:23, *Jones v. C. R. Bard, Inc.* (D. Ariz. May 16, 2018). Based on this concern, Plaintiffs argued at various points during the trial that Defendants had opened the door to presenting evidence about Recovery cephalad migration deaths. The Court repeatedly made fact-specific determinations on this point, and held that even though Defendants presented some evidence that made the Recovery evidence more relevant, the danger of unfair prejudice continued to substantially outweigh the probative value of the evidence. *See* Docs. 11113, 11302; Trial Tr. Day 10, at 2224:3 to 2226:24, *Jones v. C. R. Bard, Inc.* (D. Ariz. May 30, 2018).

d. Simon Nitinol Filter Evidence.

Plaintiffs sought to exclude evidence of complications associated with the SNF on the grounds that Plaintiffs were barred from conducting relevant discovery into the design and testing of the SNF under CMO No. 10 (Doc. 1319). The Court denied Plaintiffs' request. Doc. 10489. The Court did not agree that Plaintiffs were foreclosed from obtaining relevant evidence for rebuttal. The Court had foreclosed this discovery because Plaintiffs do not contend that the SNF is defective. *Id.* at 2. Nor did Plaintiffs explain how discovery into the design and testing of the SNF would have produced any information on failure rates the SNF experienced after it was on the market. *Id.* at 2-3. Plaintiffs also had rebuttal evidence showing that reported failure rates for the SNF were lower than Recovery and G2 failure rates. *Id.* The Court ultimately concluded it would not preclude Defendants from presenting its SNF evidence on the basis of a discovery ruling and invited Plaintiffs to make appropriate evidentiary objections at trial. *Id.* at 3.

e. Use of Testimony of Withdrawn Experts.

Defendants sought to preclude, under Federal Rules of Evidence 804 and 403, Plaintiffs' use at trial of the depositions of three defense expert witnesses, Drs. Moritz, Rogers, and Stein, who originally were retained by Bard but had since been withdrawn in some or all cases. Doc. 10255 at 2. The Court denied the request in part. Doc. 10382. The Court found that Defendants failed to show that the depositions of these experts are inadmissible on hearsay grounds, but agreed that it would be unfairly prejudicial under Rule 403 to disclose to the jury that the experts originally were retained by Bard. *Id.* at 2-3. The Court therefore concluded that Plaintiffs could use portions of the experts' depositions that support Plaintiffs' claims, but could not disclose to the jury that the experts originally were retained by Bard. *Id.* at 3. The Court was concerned about the presentation of cumulative evidence, and therefore required Plaintiffs to show that no other expert of similar qualifications is available or that the unavailable expert has some unique testimony to contribute, before the deposition of any withdrawn expert may be used at trial. *Id.* at 3-4.

f. Other Motion in Limine Rulings.

The Court's other motion in limine rulings (Docs. 10075, 10235, 10258, 10947) may be useful in other jurisdictions. The Court refers the transferor courts to the following motions and orders to assist in preparing for trial:[5]

- **Parties' Joint Stipulation on Motions in Limine in Booker:** The Court, on stipulation of the parties, excluded evidence, argument, and testimony concerning several case-specific issues in the Booker bellwether trial, as well as a few general issues, including: Bard's 1994 criminal conviction; other lawsuits or claims against Bard; advertising by Plaintiff's counsel; Plaintiffs' counsel specializing in personal injury or products liability litigation; contingency fee agreements; and advertising by any counsel nationally for any IVC filter cases. Doc. 10235.

[5] The Court also ruled on the parties' motions in limine concerning several case-specific issues. *See* Docs. 10075 (Plaintiff's MIL No. 12 in Booker), 10258 (Plaintiff's MIL Nos. 6 and 13 in Booker), 10947 (Defendants' MIL No. 1 and Plaintiff's MIL Nos. 1-4 and 7 in Jones).

- **Defendants' MIL No. 1 in Booker:** The Court permitted evidence and testimony concerning Recovery filter complications. Doc. 10258 at 1-5; *see* Doc. 10819 (Jones). As noted above, the Court permitted evidence and testimony concerning Recovery filter cephalad migrations resulting in patient death in the Booker bellwether trial involving a G2 Filter (Doc. 10323 at 4), but excluded such evidence in the Jones bellwether trial involving an Eclipse filter (Docs. 10819, 10920, 11041).

- **Defendants' MIL No. 2 in Booker:** The Court permitted evidence and testimony relating to the development of the Recovery filter. Doc. 10258 at 5-6; *see* Doc. 10819 at 2-3 (Jones).

- **Defendants' MIL No. 4 in Booker:** The Court excluded evidence and testimony concerning a photograph of Bard employee Michael Randall making an offensive gesture to a camera. Doc. 10075 at 1-2.

- **Defendants' MIL No. 5 in Booker:** The Court permitted Plaintiff's expert Dr. Thomas Kinney to be called as a fact witness, but prohibited him from testifying regarding his prior work for Bard as an expert witness in two prior IVC filter cases or as a paid consultant to Bard. Docs. 10075 at 2-3, 10323 at 4.

- **Plaintiff's MIL No. 2 in Booker:** The Court reserved ruling until trial on evidence and testimony regarding the nature of Bard's business, including the nature, quality, and usefulness of its products, the conscientiousness of its employees, and references to its mission statement. Doc. 10075 at 3-4.

- **Plaintiff's MIL No. 3 in Booker:** The Court permitted evidence and testimony concerning the benefits of IVC filters, including testimony describing Bard filters as "lifesaving" devices. Doc. 10258 at 8.

- **Plaintiff's MIL No. 4 in Booker:** The Court permitted evidence and testimony that IVC filters, including Bard filters, are within the standard of care for the medical treatment of pulmonary embolism. Doc. 10258 at 8-9. Defendants agreed to not characterize IVC filters as the "gold standard" for the treatment of pulmonary embolisms. *Id.* at 8.

- **Plaintiff's MIL No. 5 in Booker:** The Court denied as moot the motion to exclude evidence and argument relating to failure rates, complication rates, percentages, or comparative analysis of any injuries that were not produced to Plaintiffs during discovery, as all such information was produced. Doc. 10075 at 4.

- **Plaintiff's MIL No. 7 in Booker:** The Court excluded evidence and argument relating to prior judicial opinions about Plaintiff's experts, including the number of times their testimony has been precluded in other cases. *Id.*

- **Plaintiff's MIL No. 8 in Booker:** The Court excluded evidence and argument that a verdict against Defendants will have an adverse impact on the medical community, future medical device research or costs, and the availability of medical care. *Id.* at 4-5.

- **Plaintiff's MIL No. 9 in Booker:** The Court deferred ruling on the relevance of statements or lack of statements from medical societies, including the Society of Interventional Radiologists ("SIR"), until trial. Doc. 10258 at 14-18. The Court ultimately admitted this evidence in both the Booker and Jones bellwether trials.

- **Plaintiff's MIL No. 10 in Booker:** The Court excluded evidence and testimony that Bard needed FDA consent to add warnings to its labels, send warning letters to physicians and patients, or recall its filters. *Id.* at 18-19. The Court permitted evidence and argument explaining the reasons why Bard filters were not recalled, FDA's potential involvement in any recall effort, and the fact that warnings about failure rates and increased risks could not be based on MDR and MAUDE data alone. *Id.*

- **Plaintiff's MIL No. 11 in Booker:** The Court permitted evidence and argument relating to the informed consent form signed by Plaintiff prior to insertion of the IVC filter, even though the form is not specific to IVC filters or Bard filters. Doc. 10075 at 5-6

- **Plaintiff's MIL No. 14 in Booker:** The Court reserved ruling until trial on evidence and argument relating to background information and personal traits of Bard employees and witnesses. *Id.* at 7.

- **Plaintiff's MIL No. 6 in Jones:** The Court permitted evidence and testimony concerning whether a party's expert had been retained by the same attorneys in other litigation. Doc. 10947 at 8-9.

- **Plaintiff's MIL No. 5 in Jones:** The Court excluded evidence and testimony that Bard employees or their relatives have received Bard IVC filter implants. *Id.* at 9-10.

- **Defendants' MIL No. 2 in Jones:** The Court excluded evidence and testimony of other lawsuits against Bard. *Id.* at 11.

6. Deposition Designation Rulings.

The Court has ruled on numerous objections to deposition designations for trial and refers the transferor courts to the following orders:[6]

Deponent	Depo. Date	Doc. No(s).
Bill Altonaga	10/22/2013	10497, 10922
Christine Brauer	05/23/2014 08/02/2017	10922, 10922
David Ciavarella	11/12/2013	10403
Gary Cohen	01/25/2017	10438
Robert Cortelezzi	11/11/2016	10438, 11064
Len DeCant	05/24/2016	10438, 11080
John DeFord	06/02/2016	10524, 11080
Mary Edwards	01/20/2014	10438
Robert Ferrara	04/17/2017	10438
Chris Ganser	10/11/2016	10438, 11073
Jason Greer	08/11/2014	10438, 10922
Janet Hudnall	11/01/2013	10403
Brian Hudson	01/17/2014	10403
John Lehmann	08/07/2014	10922
William “Bill” Little	07/27/2016	10438, 11064
John McDermott	02/05/2014	10438

[6] In addition to the depositions identified in the table, the Court ruled on numerous objections to case-specific deposition designations for trial.

Deponent	Depo. Date	Doc. No(s).
Patrick McDonald	07/29/2016	10486, 11064
Mark Moritz	07/18/2017	10922
Daniel Orms	08/16/2016	10403, 11073
Abithal Raji-Kubba	07/18/2016	11064
Gin Schulz	01/30/2014	10403
Christopher Smith	08/03/2017	11073
William Stavropoulos	02/01/2017	10524
Jack Sullivan	11/03/2016 09/16/2016	10486, 11080
Melanie Sussman	04/07/2017	11073
Mehdi Syed	03/02/2018	11313
Scott Trerotola	01/20/2017	10524
Douglas Uelmen	10/04/2013	10403, 11080
Carol Vierling	05/11/2016	10486, 11073
Mark Wilson	01/31/2017	10922
Natalie Wong	10/18/2016	10403

I. Further Proceedings in Remanded Cases.

1. General Discovery.

Because all general fact and expert discovery has been completed in this MDL, the transferor courts need not be concerned with facilitating general expert, corporate, and third-party discovery on remand. This is not meant to restrict the power of transferor courts for good cause or in the interest of justice to address issues that may be unique and relevant in remanded cases.

2. Case-Specific Discovery and Trial Preparation.

According to the parties, the status of the remaining discovery and other pretrial issues for the cases being remanded, and the estimated time needed to resolve such issues and make the cases ready for trial, are listed in Exhibit 2. Final trial preparation in the bellwether trials was governed by certain Court orders. *See* Docs. 8871, 10323, 10587, 11011, 11320, 11321.

J. Documents to Be Sent to Transferor Courts.

If the Panel agrees with the Court's suggestion of remand of the 10 mature cases and issues a final remand order ("FRO"), the Clerk of the Court for this District will issue a letter to the transferor courts, via email, setting out the process for transferring the individual cases listed in the FRO. The letter and certified copy of the FRO will be sent to each transferor court's email address.

Upon receipt of the FRO, the parties shall furnish to the Clerk for this District a stipulation or designation of the contents of the record or part thereof to be remanded. *See* J.P.M.L Rule 10.4(a). The Clerk shall transmit to the respective transferor court the following concerning each remanded action: (1) a copy of the individual docket sheet for each action remanded, (2) a copy of the master docket sheet in this MDL, (3) the entire file for each action remanded, as originally received from the transferor district, (4) a copy of any final pretrial order entered in the remanded action (if applicable), and (5) a "record on remand" as designated by the parties. *See* J.P.M.L Rule 10.4(b).

If a party believes that the docket sheet for a particular case being remanded is not correct, a party to that case may, with notice to all other parties in the case, file with the transferor court a designation amending the record. Upon receiving such designation, the transferor court may make any needed changes to the docket. If the docket is revised to include additional documents, the parties should provide those documents to the transferor court.

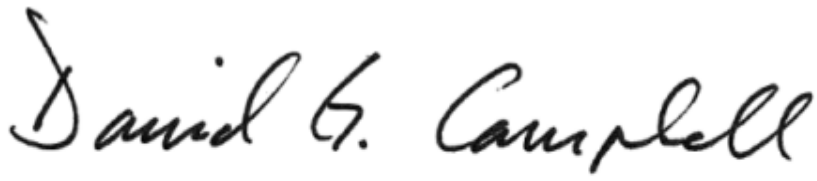
K. Conclusion.

Pursuant to J.P.M.L. Rule 10.1(b)(i), the Court suggests that the Panel remand the

10 mature cases listed on Schedule A to their transferor districts for further proceedings. The Clerk shall forward a certified copy of this order to the Panel.

IT IS SO ORDERED.

Dated this 7th day of September, 2018.



David G. Campbell
Senior United States District Judge

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION MDL NO. 2641

SCHEDULE A

Suggestion of Remand Cases

Middle District of Florida

Tillman v. C. R. Bard, Inc., No. 3:13-cv-0222
Ocasio v. C. R. Bard, Inc., No. 8:13-cv-01962

Northern District of Georgia

Cason v. C. R. Bard, Inc., No. 1:12-cv-01288
Coker v. C. R. Bard, Inc., No. 1:13-cv-00515

Eastern District of Michigan

Rivera (McClarty) v. C. R. Bard, No. 4:14-cv-13627

Eastern District of Pennsylvania

Ebert v. C. R. Bard, Inc., No. 5:12-cv-01253
Keen v. C. R. Bard, Inc., No. 5:13-cv-05361

Eastern District of Texas

Smith v. C. R. Bard, Inc., No. 1:13-cv-00633

Northern District of Texas

Fox v. C. R. Bard, Inc., No. 3:14-cv-00133

Eastern District of Wisconsin

Henley v. C. R. Bard, Inc., No. 2:14-cv-00059

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION MDL NO. 2641

EXHIBIT 1

MDL Orders

CASE MANAGEMENT ORDERS		
Date Filed	**Docket No**	**Docket Text**
10/30/2015	248	Case Management Order No. 1 re Leadership Counsel Appointments
11/16/2016	4016	Amended Case Management Order No. 1 re Leadership Counsel Appointments
03/21/2017	5285	Second Amended Case Management Order No. 1 re Plaintiff Leadership Team
10/30/2015	249	Case Management Order No. 2 re Setting Deadlines, First Phase of Discovery
12/01/2015	314	Case Management Order No. 3 re Non-waiver Order Pursuant to Rule 502(d)
12/17/2015	363	Case Management Order No. 4 re Master Complaint, Responsive Pleadings, Short Form Complaint, Waiver, and Answer
12/17/2015	365	Case Management Order No. 5 re Plaintiff and Defendant Profile Forms
03/03/2016	927	Amended Case Management Order No. 5 re Plaintiff and Defendant Profile Forms
12/18/2015	372	Case Management Order No. 6 re Rules to Establishing Common Benefit Fee
01/05/2016	401	Case Management Order No. 7 re Stipulations Concerning Redactions
02/02/2016	519	Case Management Order No. 8 re Second Phase of Discovery
03/31/2016	1259	Case Management Order No. 9 re Electronically Stored Information and production protocol
04/01/2016	1319	Case Management Order No. 10 re Second Phase Discovery, Bellwether, ESI, FDA, Deposition, and Privilege Log
05/05/2016	1662	Case Management Order No. 11 re Bellwether Selection Process
05/05/2016	1663	Case Management Order No. 12 re Joint Record Collection
06/21/2016	2238	Case Management Order No. 13 re ESI, FDA Warning Letter and Designations
06/21/2016	2239	Case Management Order No. 14 re Deposition Protocols
08/25/2016	3214	Case Management Order No. 15 re Lexecon Waivers, ESI Discovery, Multi-plaintiff Actions, and Deceased Plaintiffs
08/25/2016	3215	Case Management Order No. 16 re Deadlines Related to Barraza

12/02/2016	4141	Amended Case Management Order No. 16 re Deadlines Related to Barraza
09/14/2016	3372	Case Management Order No. 17 re Protective Order and Expedited ESI Production
11/16/2016	4015	Amended Case Management Order No. 17 re Protective Order and Redactions of Material from Expedited ESI Production
10/17/2016	3685	Case Management Order No. 18 re Adjusted Discovery Schedule
12/13/2016	4311	Case Management Order No. 19 re ESI and Bellwether Selection
12/22/2016	4335	Case Management Order No. 20 re Discovery Deadlines for Discovery Group 1 and Bellwether Group 1
02/06/2017	4866	Case Management Order No. 21 re Discovery Protocols for Discovery Group 1
02/17/2017	5007	Case Management Order No. 22 re Setting Deadlines
05/05/2017	5770	Case Management Order No. 23 re Expert Deposition Deadlines, Bellwether Case Selection, Preemption Motion for Summary Judgment, and Mature Cases
05/19/2017	5881	Case Management Order No. 23 re Discovery Protocols for Bellwether Group 1
05/19/2017	5883	Amended Case Management Order No. 24 re Discovery Protocols for Bellwether Group 1
06/06/2017	6227	Case Management Order No. 25 re Bellwether Group 1 Amended Discovery Schedule
07/17/2017	6799	Case Management Order No. 26 re Depositions of Dr. Henry and Dr. Altonaga, Communications among Plaintiffs' Experts, and Bellwether Trial Issues
10/10/2017	8113	Case Management Order No. 27 re Privilege Issues, Bellwether Trial Schedule, Plaintiffs' Motion for Partial Summary Judgment, and Recusal Unnecessary
11/21/2017	8871	Case Management Order No. 28 re Booker Bellwether Trial Schedule, and Mature Cases
12/21/2017	9415	Case Management Order No. 29 re Booker Bellwether Trial Schedule, Motion to Certify Appeal, and *Cisson* Motion Briefing
01/23/2018	9775	Case Management Order No. 30 re Motions Hearings, Motions in Limine, and Punitive Damages in Booker
03/02/2018	10323	Case Management Order No. 31 re Booker Trial
05/07/2018	11011	Case Management Order No. 32 re Jones Trial
06/01/2018	11320	Case Management Order No. 33 re Mulkey as Next Bellwether Selection, and Mulkey Trial Schedule
06/28/2018	11659	Case Management Order No. 34 re Next 3 Bellwether Trials, Kruse Trial Schedule, Use of Dr. Kandarpa at Trial, Sixth Bellwether Tinlin, Disposition of SNF Cases, and Remand of Mature Cases
07/13/2018	11871	Case Management Order No. 35 re September, November and May Bellwether Trials, and Hyde September Bellwether Trial Schedule

08/02/2018	12061	Case Management Order No. 36 re Tinlin Bellwether Pre-trial Schedule

DISCOVERY ORDERS

Date Filed	Docket No	Docket Text
10/30/2015	249	Case Management Order No. 2 re Setting Deadlines, First Phase of Discovery
02/02/2016	519	Case Management Order No. 8 re Second Phase of Discovery
03/31/2016	1259	Case Management Order No. 9 re Electronically Stored Information and production protocol
04/01/2016	1319	Case Management Order No. 10 re Second Phase Discovery, Bellwether, ESI, FDA, Deposition, and Privilege Log
05/05/2016	1663	Case Management Order No. 12 re Joint Record Collection
06/21/2016	2238	Case Management Order No. 13 re ESI, FDA Warning Letter and Designations
06/21/2016	2239	Case Management Order No. 14 re Deposition Protocols
08/25/2016	3214	Case Management Order No. 15 re Lexecon Waivers, ESI Discovery, Multi-plaintiff Actions, and Deceased Plaintiffs
08/29/2016	3272	Order re Deposition of Jim Beasley
09/06/2016	3312	Order re discovery disputes concerning Plaintiffs' communications with FDA
09/06/2016	3313	Order re Plaintiffs' communications with NBC or other media outlets and admissibility at trial
09/06/2016	3314	Order re Plaintiffs' third party funding arrangements
09/14/2016	3372	Case Management Order No. 17 re Protective Order and Expedited ESI Production
11/16/2016	4015	Amended Case Management Order No. 17 re Protective Order and Redactions of Material from Expedited ESI Production
09/16/2016	3398	Order re ESI generated by foreign entities that sell filters abroad
10/17/2016	3685	Case Management Order No. 18 re Adjusted Discovery Schedule
12/13/2016	4311	Case Management Order No. 19 re ESI and Bellwether Selection
12/22/2016	4335	Case Management Order No. 20 re Discovery Deadlines for Discovery Group 1 and Bellwether Group 1
12/24/2016	4339	Order re proposed depositions of and interrogatories to Plaintiffs' counsel
02/06/2017	4865	Order re discovery dispute on ex parte communications with treating physicians and depositions of treating physicians and sales representatives
02/06/2017	4866	Case Management Order No. 21 re Discovery Protocols for Discovery Group 1
05/05/2017	5770	Case Management Order No. 23 re Expert Deposition Deadlines, Bellwether Case Selection, Preemption Motion for Summary Judgment, and Mature Cases

05/19/2017	5881	Case Management Order No. 23 re Discovery Protocols for Bellwether Group 1
05/19/2017	5883	Amended Case Management Order No. 24 re Discovery Protocols for Bellwether Group 1
06/06/2017	6227	Case Management Order No. 25 re Bellwether Group 1 Amended Discovery Schedule
07/17/2017	6799	Case Management Order No. 26 re Depositions of Dr. Henry and Dr. Altonaga, Communications among Plaintiffs' Experts, and Bellwether Trial Issues

DISCOVERY AND PRIVILEGE ORDERS

Date Filed	Docket No	Docket Text
12/01/2015	314	Case Management Order No. 3 re Non-waiver Order Pursuant to Rule 502(d)
02/11/2016	699	Order re Motion for Protective Order concerning Dr. John Lehmann's December 15, 2004, report as protected work product
07/25/2016	2813	Order re Plaintiffs' Motion to Compel (Privilege Log Issues)
02/06/2017	4865	Order re discovery dispute on ex parte communications with treating physicians and depositions of treating physicians and sales representatives
07/17/2017	6799	Case Management Order No. 26 re Depositions of Dr. Henry and Dr. Altonaga, Communications among Plaintiffs' Experts, and Bellwether Trial Issues
10/10/2017	8113	Case Management Order No. 27 re Privilege Issues, Bellwether Trial Schedule, Plaintiffs' Motion for Partial Summary Judgment, and Recusal Unnecessary
10/20/2017	8315	Order that Plaintiffs need not produce the withheld expert communications or provide a privilege log on these communications to Defendants.

DAUBERT ORDERS

Date Filed	Docket No	Docket Text
12/21/2017	9428	Order re Motion to Disqualify Plaintiffs' Expert Thomas Kinney, M.D.
12/21/2017	9432	Order re Motion to Disqualify Plaintiffs' Experts Drs. Resnick, Vogelzang, and Desai
12/22/2017	9433	Order re Motion to Exclude Plaintiffs' Experts Drs. Parisian and Kessler
12/22/2017	9434	Order re Motion to Exclude Plaintiffs' Experts Drs. Kinney, Roberts, and Kalva
01/22/2018	9770	Order re Motion to Exclude Plaintiffs' Expert Dr. Eisenberg
01/22/2018	9771	Order re Motion to Exclude Plaintiffs' Expert Dr. Muehrcke
01/22/2018	9772	Order re Motion to Exclude Plaintiffs' Expert Dr. Hurst
01/22/2018	9773	Order re Motion to Exclude Plaintiffs' Expert Dr. Betensky

02/06/2018	9991	Order re Motion to Exclude Bard's Expert Dr. Grassi
02/08/2018	10051	Order re Motion to Exclude Plaintiffs' Expert Dr. McMeeking
02/08/2018	10052	Order re Motion to Exclude Plaintiffs' Expert Dr. Ritchie
02/12/2018	10072	Order re Motion to Exclude Plaintiffs' Experts Drs. Garcia and Streiff
02/21/2018	10230	Order re Motion to Exclude Bard's Experts Drs. Grassi and Morris
02/21/2018	10231	Order re Motion to Exclude Bard's Expert Dr. Morris

MOTIONS IN LIMINE ORDERS

Date Filed	Docket No	Docket Text
01/23/2018	9775	Case Management Order No. 30 re Motions Hearings, Motions in Limine, and Punitive Damages in Booker
01/26/2018	9861	Joint Stipulation re prohibiting raising certain issues in the presence of the jury for Booker Bellwether case
01/29/2018	9881	Order re admissibility of (1) pre-market clearance of Bard IVC filters by FDA and (2) the lack of FDA Enforcement Action against Bard
02/15/2018	10075	Order re Motions in Limine re Photographs of Mike Randall, Dr. Kinney work for Bard, Benevolent Activities, Evidence Not Produced in Complaint Files, Prior Judicial Opinions, Adverse Impact of a Plaintiff's Verdict, Informed Consent Form, Dr. Kang Social Media Posts, Personal Traits of Employees and Witnesses for Booker Bellwether case
02/22/2018	10235	Order re Parties' Joint Stipulation re prohibiting raising certain issues in the presence of the jury for Booker Bellwether case
03/01/2018	10258	Order re Motions in Limine re Recovery® Filter Complications, Recovery® Filter Development, FDA Warning Letter, IVC Filter as Lifesaving Devices, IVC filters are Gold Standard, Nonparties at Fault, Statements from Associations and Other Groups, FDA Consent for Warnings or Recalls for Booker Bellwether case
03/09/2018	10382	Order re Plaintiff's use of the depositions of Drs. Moritz, Rogers, and Stein at trial
03/19/2018	10489	Order re Simon Nitinol Filter complication evidence
04/18/2018	10819	Order re reconsideration motions relating to Recovery® Filter Evidence and cephalad Migration Deaths for Jones Bellwether case
04/27/2018	10920	Order re Plaintiff’s motion for reconsideration of Court Order excluding evidence of Recovery® Filter Cephalad Migration Deaths for Jones Bellwether case
05/03/2018	10947	Order re Motions in Limine re (1) Case Specific Medical Issues (2) Relatives receipt of IVC Filters, (3) Experts Retained In Other Litigation, (4) Attorney Advertising, (5) Other Lawsuits for Jones Bellwether case
05/08/2018	11041	Order re cephalad migration deaths for Jones Bellwether case

05/15/2018	11082	Order re reconsideration of Recovery migration deaths
05/29/2018	11256	Order re cephalad migration, Recovery filter and deaths and FDA evidence for Jones Bellwether case

DEPOSITION DESIGNATION ORDERS

Date Filed	Docket No	Docket Text
03/07/2018	10348	Order re deposition designations for Booker Bellwether case
03/12/2018	10403	Order re deposition designations for Booker Bellwether case
03/14/2018	10438	Order re deposition designations for Booker Bellwether case
03/19/2018	10486	Order re deposition designations for Booker Bellwether case
03/21/2018	10497	Order re deposition designations for Booker Bellwether case
03/26/2018	10524	Order re deposition designations for Booker Bellwether case
05/01/2018	10922	Order re deposition designations for Jones Bellwether case
05/10/2018	11064	Order re deposition designations for Jones Bellwether case
05/11/2018	11073	Order re deposition designations for Jones Bellwether case
05/14/2018	11080	Order re deposition designations for Jones Bellwether case
05/31/2018	11313	Order re deposition designations for Jones Bellwether case

MISCELLANEOUS ORDERS

Date Filed	Docket No	Docket Text
11/10/2015	269	Amended Stipulated Protective Order re Confidentiality
11/22/2017	8872	Order re Bard's Motion for Summary Judgment on Preemption Grounds
11/22/2017	8874	Order re Bard's Motion for Summary Judgment for Booker Bellwether case
03/12/2018	10404	Order re Bard's Motion for Summary Judgment for Jones Bellwether case
03/30/2018	10587	Order re final trial preparation and setting Final Pretrial Conference for Jones Bellwether case.
06/01/2018	11321	Order re final trial preparation and setting Final Pretrial Conference for Mulkey Bellwether case.

EXHIBIT 2

Parties' Proposed Case-Specific Trial Readiness Steps and Estimated Time

While certain fact and expert discovery was conducted in the 10 mature cases prior to the formation of the MDL, the Court directed the parties that further case-specific discovery in these cases should await their remand. Docs. 3214, at 3; 8871 at 5. Fact and expert discovery and certain motions practice remains to be done, or updated, in these cases. As to the steps needed to make the cases trial ready, Defendants report as follows:

With the exception of the disputed actions noted below, the parties agree as to the steps required for remaining fact and expert discovery, and motions practice, in these cases. The parties intend to substitute MDL generic experts for previously designated generic experts in these cases, with rare exceptions. Should a party request to add another expert, the parties have agreed to meet and confer on the request, and failing agreement, to seek a ruling by motion to the transferor court for permission to add the expert, and allow the transferor court to rule on the request. The parties disagree on whether the showing required for such request is "good cause" or "exceptional circumstances."

If previously designated experts have already been deposed and *Daubert* rulings issued, the parties agree that these experts may update their reports to include MDL discovery and the parties may depose such experts on the supplemental portions of their reports. The parties will meet and confer on whether new *Daubert* challenges are warranted. The parties agree that there will be no new *Daubert* motions as to generic experts who were designated in the MDL. Any additional *Daubert* motions filed in these cases will be limited to case-specific experts, and any such motion will be filed only if the time in which to file such motions in the transferor court had not passed and if there was no ruling on a prior *Daubert* motion filed in the case as to that expert. The parties

also agree that the time needed to complete fact and expert discovery in each case is approximately 180 days. The parties have agreed to request a case management conference with the transferor court in each case to discuss which of the MDL court's motion in limine rulings the transferor court intends to adopt, or declines to adopt, based on application of the state law applicable to each case.

Disputed Issues

Disputed Issue	**Plaintiffs' Position**	**Defendants' Position**
Updated depositions of corporate and third party witnesses	Plaintiffs' position is that limited additional depositions of corporate and third party witnesses may be appropriate in some cases with unique facts not covered in the MDL generic deposition of that witness. Plaintiffs believe that the transferor court can make decisions as to the propriety of such additional depositions.	Defendants' position is that a purpose of the MDL was to manage all generic discovery relevant to the litigation. Defendants object to Plaintiffs taking additional depositions of corporate or third party witnesses in these cases as it amounts to discovery that was permitted by the MDL Court and should have been done in discovery in the MDL.
Updated depositions of implanting physicians, physicians who prescribed the Bard filter, and treating physicians	Plaintiffs' position is that this should be in the sound discretion of the transferor court as it involves case-specific issues. Plaintiffs reserve the right to re-depose these categories of treating physicians based on discovery that has occurred since the formation of this MDL, which has had jurisdiction over these cases during its pendency, and which discovery, in part, was the basis of these cases not being remanded earlier. Plaintiffs submit that	Defendants' position is that re-deposition of implanters or other treaters in these cases is not appropriate except to elicit information from those treaters relating to care provided to Plaintiffs since the time of transfer of the case, which testimony is relevant to causation or damages. Should Plaintiffs request deposition of any treater previously deposed in the case, the parties must meet and confer on the request and, failing agreement, the party seeking

Disputed Issue	Plaintiffs' Position	Defendants' Position
	prejudice to these early remands having been removed from their existing trial track for almost 3 years would be compounded if they were singled out as the only MDL-transferred cases that would not have the benefit of such additional discovery.	such deposition shall seek a ruling, by motion to the transferor court, for permission to take such deposition, demonstrating good cause under the criteria required by FRCP 30(a)(2)(A)(ii) and 26(b)(1) and (2).
Showing required to request designation of a new expert who is neither an MDL designated expert nor an expert designated in the case prior to transfer	Plaintiffs' position is that the necessary showing should be "good cause."	Defendants' position is that the necessary showing should be "exceptional circumstances."
Defendants' Motion for 502(d) Order Protecting Any Attorney Client Privilege and Work Product Revealed Regarding Upcoming Motion for Protective Order (Lehman)	Plaintiffs believe that in the cases where the transferor court has not ruled on the issues presented in this motion, that Plaintiffs are entitled to a ruling from the transferor court applying the law applicable to the case.	Defendants' position is that the MDL Court previously ruled that "the parties agree that this Court's ruling should not affect prior rulings on this issue in other cases. *See* Docs. 306 at 21-23, 379 at 29-30. This ruling shall operative prospectively only, and shall apply in all MDL cases where the issue has not previously been decided." Doc. 699 at 22. As such, to the extent that a transferor court has not ruled on these issues, the MDL Court's ruling must apply and Plaintiffs may not reargue the issue in the transferor court.